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**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

ASTRAZENECA LP and ASTRAZENECA AB,  
Plaintiffs,  
v.  
BREATH LIMITED,  
Defendant.

) Consolidated Civil Action No. 08 CV 1512  
) (RMB)(AMD)

ASTRAZENECA LP and ASTRAZENECA AB,  
Plaintiffs,  
v.  
APOTEX, INC. and APOTEX CORP.,  
Defendants.

## **REPLY TO COUNTERCLAIMS**

Plaintiffs AstraZeneca LP and AstraZeneca AB (collectively, “AstraZeneca”) reply to defendant Breath Limited’s (“Breath’s”) Counterclaims set forth in its July 9, 2009 Answer, Defenses, and Counterclaims to Amended Complaint (“Counterclaims”) as follows:

### **THE PARTIES**

1. AstraZeneca admits the allegations set forth in Paragraph 1 of the Counterclaims.
2. AstraZeneca admits the allegations set forth in Paragraph 2 of the Counterclaims.
3. AstraZeneca admits, upon information and belief, the allegations set forth in Paragraph 3 of the Counterclaims.

### **JURISDICTION AND VENUE**

4. AstraZeneca admits that Breath purports to state Counterclaims for declaratory judgment arising under 28 U.S.C. §§ 2201 and 2202. AstraZeneca admits that Breath’s Counterclaims arise under the patent laws of the United States, 35 U.S.C. §§ 1, et seq. AstraZeneca denies the remaining allegations set forth in Paragraph 4 of the Counterclaims.
5. AstraZeneca admits the allegations set forth in Paragraph 5 of the Counterclaims.
6. AstraZeneca does not contest that it is subject to personal jurisdiction in this judicial district with respect to the Counterclaims. AstraZeneca denies the remaining allegations set forth in Paragraph 6 of the Counterclaims.
7. AstraZeneca does not contest that venue is proper in this district with respect to Breath’s Counterclaims. AstraZeneca denies the remaining allegations set forth in Paragraph 7 of the Counterclaims.

### THE PATENTS-IN-SUIT

8. AstraZeneca admits that U.S. Patent No. 6,598,603 (“the ‘603 patent”), entitled “METHOD FOR TREATING RESPIRATORY DISEASES,” issued on July 29, 2003, naming Bertil Andersson, Thor-Bjorn Conradsson, and Goran Eriksson as the inventors. AstraZeneca denies the remaining allegations set forth in Paragraph 8 of the Counterclaims.

9. AstraZeneca admits that U.S. Patent No. 6,899,099 (“the ‘099 patent”), entitled “METHOD FOR TREATING A RESPIRATORY DISEASE,” issued on May 31, 2005, naming Bertil Andersson, Thor-Bjorn Conradsson, and Goran Eriksson as the inventors. AstraZeneca denies the remaining allegations set forth in Paragraph 9 of the Counterclaims.

10. AstraZeneca admits that U.S. Patent No. 7,524,834 (“the ‘834 patent”), entitled “STERILE POWDERS, FORMULATIONS, AND METHODS FOR PRODUCING THE SAME,” issued on April 28, 2009, naming Ann-Kristin Karlsson, Cheryl Larrivee-Elkins, and Ove Molin as the inventors. AstraZeneca denies the remaining allegations set forth in Paragraph 10 of the Counterclaims.

11. AstraZeneca admits that AstraZeneca AB is the owner of all right, title, and interest in and to U.S. Patent Nos. 6,899,099, 6,598,603, and 7,524,834. AstraZeneca admits that it has the right to enforce such patents. AstraZeneca denies the remaining allegations set forth in Paragraph 11 of the Counterclaims.

12. AstraZeneca admits that it sued Breath in this district by filing on March 19, 2008 a Complaint for Breath’s infringement of the ‘603 and ‘099 patents. AstraZeneca admits that its Complaint asserted *inter alia* that Breath’s submission of ANDA No. 78-404 was an act of infringement of one or more claims of the ‘603 and ‘099 patents, under the United States Patent Law, 35 U.S.C. § 271(e)(2)(A). AstraZeneca also admits that it filed on June 29, 2009 an Amended Complaint for Breath’s infringement of the ‘603 and ‘099 patents and seeking

*inter alia* a declaration that Breath will infringe one or more claims of the ‘834 patent.

AstraZeneca denies the remaining allegations set forth in Paragraph 12 of the Counterclaims.

### **REPLY TO BREATH’S COUNT I**

13. AstraZeneca repeats and incorporates by reference its reply to Paragraphs 1 through 12 herein. To the extent that Breath’s First through Sixth defenses are incorporated into Breath’s counterclaims, AstraZeneca denies the allegations set forth in Breath’s defenses.

14. AstraZeneca admits that a justiciable controversy exists as to the infringement of the ‘603 patent. AstraZeneca denies the remaining allegations set forth in Paragraph 14 of the Counterclaims.

15. AstraZeneca denies the allegations set forth in Paragraph 15 of the Counterclaims.

16. AstraZeneca denies the allegations set forth in Paragraph 16 of the Counterclaims.

### **REPLY TO BREATH’S COUNT II**

17. AstraZeneca repeats and incorporates by reference its reply to Paragraphs 1 through 16 herein.

18. AstraZeneca admits that a justiciable controversy exists as to the infringement of the ‘099 patent. AstraZeneca denies the remaining allegations set forth in Paragraph 18 of the Counterclaims.

19. AstraZeneca denies the allegations set forth in Paragraph 19 of the Counterclaims.

20. AstraZeneca denies the allegations set forth in Paragraph 20 of the Counterclaims.

**REPLY TO BREATH'S COUNT III**

21. AstraZeneca repeats and incorporates by reference its reply to Paragraphs 1 through 20 herein.

22. AstraZeneca admits that a justiciable controversy exists as to the infringement of the '834 patent. AstraZeneca denies the remaining allegations set forth in Paragraph 22 of the Counterclaims.

23. AstraZeneca denies the allegations set forth in Paragraph 23 of the Counterclaims.

24. AstraZeneca denies the allegations set forth in Paragraph 24 of the Counterclaims.

**REPLY TO BREATH'S COUNT IV**

25. AstraZeneca repeats and incorporates by reference its reply to Paragraphs 1 through 24 herein.

26. AstraZeneca admits that a justiciable controversy exists as to the validity of the '603 patent. AstraZeneca denies the remaining allegations set forth in Paragraph 26 of the Counterclaims.

27. AstraZeneca denies the allegations set forth in Paragraph 27 of the Counterclaims.

28. AstraZeneca denies the allegations set forth in Paragraph 28 of the Counterclaims.

**REPLY TO BREATH'S COUNT V**

29. AstraZeneca repeats and incorporates by reference its reply to Paragraphs 1 through 28 herein.

30. AstraZeneca admits that a justiciable controversy exists as to the validity of the '099 patent. AstraZeneca denies the remaining allegations set forth in Paragraph 30 of the Counterclaims.

31. AstraZeneca denies the allegations set forth in Paragraph 31 of the Counterclaims.

32. AstraZeneca denies the allegations set forth in Paragraph 32 of the Counterclaims.

#### **REPLY TO BREATH'S COUNT VI**

33. AstraZeneca repeats and incorporates by reference its reply to Paragraphs 1 through 32 herein.

34. AstraZeneca admits that a justiciable controversy exists as to the validity of the '834 patent. AstraZeneca denies the remaining allegations set forth in Paragraph 34 of the Counterclaims.

35. AstraZeneca denies the allegations set forth in Paragraph 35 of the Counterclaims.

36. AstraZeneca denies the allegations set forth in Paragraph 36 of the Counterclaims.

#### **REPLY TO BREATH'S PRAYER FOR RELIEF**

37. AstraZeneca denies that Breath is entitled to the judgment it seeks in paragraphs (a) through (i) of its Prayer For Relief.

#### **REPLY TO BREATH'S JURY DEMAND**

38. AstraZeneca denies that any issue raised in and existing as of the date of this pleading is triable to a jury.

### **AFFIRMATIVE DEFENSES TO COUNTERCLAIMS**

39. AstraZeneca repeats and incorporates by reference herein the assertions set forth in its Amended Complaint in this action and in Paragraphs 1 through 38 herein.

40. The '603 patent is valid and enforceable.

41. The '099 patent is valid and enforceable.

42. The '834 patent is valid and enforceable.

43. The manufacture, use, offer for sale and/or sale of Breath's products that are the subject of ANDA No. 78-404 will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '603 patent.

44. The manufacture, use, offer for sale and/or sale of Breath's products that are the subject of ANDA No. 78-404 will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '099 patent.

45. The manufacture, use, offer for sale and/or sale of Breath's products that are the subject of ANDA No. 78-404 will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '834 patent.

### **RELIEF**

WHEREFORE, AstraZeneca prays for judgment against defendant Breath as follows:

- A. Dismissing Breath's Counterclaims with prejudice;
- B. Awarding AstraZeneca the relief sought in its Amended Complaint;
- C. Awarding AstraZeneca its costs, attorney's fees, and expenses incurred in this action; and

D. Awarding AstraZeneca such other and further relief as this Court may deem just and proper.

Respectfully submitted,

DATED: July 27, 2009

By s/William J. Heller

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**CERTIFICATE OF SERVICE**

I, the undersigned, hereby certify that on July 27, 2009, I caused  
ASTRAZENECA'S REPLY TO COUNTERCLAIMS to be served via ECF and by electronic  
mail to:

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